MAY 21 2003

Premarket Notification 510(k) Summary
As required by section 807.92
Datex-Ohmeda S/5™ Anesthesia Monitor with L-ANE03 and L-ANE03A software

GENERAL COMPANY INFORMATION as required by 807.92(a)(1)

COMPANY NAME/ADDRESS/PHONE/FAX:

Datex-Ohmeda
86 Pilgrim Road
Needham, MA 02492 USA
Tel: 781-449-8685
Fax: 781-433-1344

NAME OF CONTACT:

Mr. Joel Kent

DATE:

March 12, 2003

DEVICE NAME as required by 807.92(a)(2)

TRADE NAME:

Datex-Ohmeda S/5™ Anesthesia Monitor with L-ANE03 and L-ANE03A software

COMMON NAME:

Patient Monitor

CLASSIFICATION NAME:

The following Class III classifications appear applicable:

DSI	Arrhythmia detector & alarm	870.1025
MLD	Monitor ST-segment & alarm	870.1025

NAME OF LEGALLY MARKETED DEVICE FOR WHICH A CLAIM OF SUBSTANTIAL EQUIVALENCE IS MADE as required by 807.92(a)(3)

The Datex-Ohmeda S/5™ Anesthesia Monitor with L-ANE03 and L-ANE03A software is substantially equivalent in safety and effectiveness to the legally marketed predicate Datex-Ohmeda S/5™ Anesthesia Monitor with L-ANE02 and L-ANE02A software (K021279).

DEVICE DESCRIPTION as required by 807.92(a)(4)

The S/5™ Anesthesia Monitor is a patient monitor, which displays the measurement of patient physiological parameters in the hospital setting. The measurement of patient physiological parameters is accomplished by specialized measurement modules which, when plugged into the frame, allow the modules to communicate with the monitor. The care giver can select from a variety of available measurements (parameters) and apply those parameters that are best suited to patient care. Modules perform the functions of parameter measurement and minor data processing. The S/5™ Anesthesia Monitor displays parameters on screen, signals alarms and performs advanced data processing. There are two software options available for the S/5™ Anesthesia Monitor: L-ANE03 and L-ANE03A. L-ANE03A is equipped with extended arrhythmia analysis capability. Other than arrhythmia analysis capabilities, this software option is identical to L-ANE03.

The modifications to the device are:

1. Support for M-Entropy module has been added. M-Entropy has its own 510(k) clearance
2. Improvement in the QRS detection with rather low QRS amplitude ECG, to avoid false Asystole alarms.
3. The definition for Ventricular Tachycardia have been modified:
   now 6 beats at a heart rate of 120 (previously 5 beats at a heart rate of 100).
4. Invasive pressure cursor added to the inv.bp waveform field. The cursor is used for marking the reference pressure levels during a monitoring period.
5. MAC (Mean Alveolar Concentration) age calculation added. User can select the calculation of age-dependent MAC values.
6. Invasive pressure Mean Arterial Pressure (Art mean) value added to vital parameters numerical trend page.
7. New catheter types added to the selection list for the Cardiac Output measurement.
8. Automatic case reset disabled during Cardio Pulmonary Bypass (CPB) mode.
9. Messages related to the communication between S/5 monitor and D-O Central have been modified. "HR limit changed" and "PVC rate changed" messages have been replaced with the message "Alarm setup changed from Central".
10. Menu and Data Card symbols and Network symbol have been modified. Layout changes have been done so that the same symbols can be displayed with all of the different display resolutions.
11. A 19" LCD display and a 43" plasma display secondary display option have been added along with a display controller specific for the 19" LCD (B-DISP19).

INTENDED USE as required by 807.92(a)(5)

Intended use:

The S/5™ Anesthesia Monitor with L-ANE03 and L-ANE03A software is intended for multiparameter patient monitoring with optional patient care documentation

Indications for use:

The S/5™ Anesthesia Monitor with L-ANE03 and L-ANE03A software is indicated for monitoring of hemodynamic (including arrhythmia and ST-segment analysis), respiratory, ventilatory, gastrointestinal/regional perfusion, Bispectral index (BIS), Entropy (State Entropy and Response entropy) and neurophysiological status of all hospital patients. The S/5™ Anesthesia Monitor with L-ANE03 and L-ANE03A software when using BIS is for monitoring the state of the brain by data acquisition and processing of electroencephalograph signals and may be used as an aid in monitoring the effects of certain anesthetic agents. The S/5™ Anesthesia Monitor with L-ANE03 and L-ANE03A software is also indicated for documenting patient care related information. The S/5™ Anesthesia Monitor with L-ANE03 and L-ANE03A software is indicated for use by qualified medical personnel only.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS OF DEVICE COMPARED TO THE PREDICATE DEVICE as required by 807.92(a)(6)

The Datex-Ohmeda S/5™ Anesthesia Monitor with L-ANE03 and L-ANE03A software is substantially equivalent to the predicate Datex-Ohmeda S/5™ Anesthesia Monitor with L-ANE02 and L-ANE02A software (K021279).

The S/5™ Anesthesia Monitor with L-ANE03 and L-ANE03A software is indicated for monitoring of hemodynamic (including arrhythmia and ST-segment analysis), respiratory, ventilatory, gastrointestinal/regional perfusion, Bispectral index (BIS), Entropy (State Entropy and Response entropy) and neurophysiological status of all hospital patients. The S/5™ Anesthesia Monitor with L-ANE03 and L-ANE03A software when using BIS is for monitoring the state of the brain by data acquisition and processing of electroencephalograph signals and may be used as an aid in monitoring the effects of certain anesthetic agents. The S/5™ Anesthesia Monitor with L-ANE03 and L-ANE03A software is also indicated for documenting patient care related information. The S/5™ Anesthesia Monitor with L-ANE03 and L-ANE03A software is indicated for use by qualified medical personnel only.

The S/5™ Anesthesia Monitor with L-ANE03 and L-ANE03A software is a modular multiparameter patient monitor providing connections to measurement modules. The general construction, intended use of the S/5™ Anesthesia Monitor with L-ANE03 and L-ANE03A software are the same as for the predicate S/5™ Anesthesia Monitor with L-ANE02 and L-ANE02A software (K021279). The indications for use for the Datex-Ohmeda S/5™ Anesthesia Monitor with L-ANE03 and L-ANE03A software are essentially the same as the predicate the only difference being that the new device supports the M-ENTROPY module and therefore Entropy has been added to the list of monitoring parameters.

Based on the above and a detailed analysis in this 510(k) and attachments it is evident that the main features and indications for use of the S/5™ Anesthesia Monitor with L-ANE03 and L-ANE03A software is substantially equivalent to the predicate S/5™ Anesthesia Monitor with L-ANE02 and L-ANE02A software (K021279).

SUMMARY OF NONCLINICAL TESTING FOR THE DEVICE and CONCLUSIONS as required by 807.92(b)(1)(3)

The Datex-Ohmeda S/5™ Anesthesia Monitor with L-ANE03 and L-ANE03A software complies with the safety standards below and is therefore safe and effective for the intended use. The device has been thoroughly tested including electrical safety, electromagnetic compatibility, mechanical and environmental tolerance, software validation and verification of specifications. Verification of compliance with the following mandatory and voluntary standards has been made:

- IEC 60601-1:1988+ Amdt.:1:1991 + Amdt. 2:1995
- EN 60601-1: 1990 + A1:1993+A2:1995+A13:1996
- CAN/CSA-C22.2 No.601.1-M90 +S1:1994+Amdt. 2:1998
- IEC 60601-2-27:1994/EN 60601-2-27:1994
- IEC 60601-2-30:1995/EN 60601-2-30:1995
- IEC 60601-2-34:1994/EN 60601-2-34:1994
- IEC 60601-2-40:1998
- IEC 60601-1-2(2001)/EN 60601-1-2
- IEC 60601-1-4: 1996+Amdt. 1:1999/EN 60601-1-4
- ISO 9918:1993/EN 864:1996
- ISO 9919:1992/EN865:1997
- ISO 7767:1997/EN12598:1999
- ISO 11196:1995 + Corr. 1:1997/EN ISO11196:1997
- IEC 601-2-10:1987/HD 395.2.10:1988 + Am.1:2000
- IEC 60601-2-26:1994/EN60601-2-26
- IEC 60068-2
- UL 2601-1:1997

- ANSI/AAMI ES-1:1993
- ANSI/AAMI EC57:1998
- FDA 21 CFR 898.12

Conclusion:

The summary above shows that there are no new questions of safety and effectiveness for the Datex-Ohmeda S/5™ Anesthesia Monitor with L-ANE03 and L-ANE03A software as compared to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 21 2003

Datex-Ohmeda
c/o Mr. Joel C. Kent
Manager, Quality and Regulatory Affairs
86 Pilgrim Road
Needham, MA 02492

Re: K030812
Trade Name: Datex-Ohmeda S/5™ Anesthesia Monitor with L-ANEØ3 and L-ANE03A software
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia detector and alarm
Regulatory Class: Class III (three)
Product Code: MHX
Dated: March 13, 2003
Received: March 14, 2003

Dear Mr. Kent:

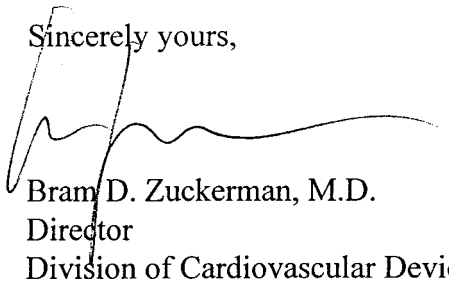
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K030812
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510(k) Number (if known): _____

Device Name: S/5™ Anesthesia Monitor with L-ANE03 and L-ANE03A software

The S/5™ Anesthesia Monitor with L-ANE03 and L-ANE03A software is indicated for monitoring of hemodynamic (including arrhythmia and ST-segment analysis), respiratory, ventilatory, gastrointestinal/regional perfusion, Bispectral index (BIS), Entropy (State Entropy and Response Entropy) and neurophysiological status of all hospital patients.

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The S/5™ Anesthesia Monitor with L-ANE03 and L-ANE03A software is also indicated for documenting patient care related information.

The S/5™ Anesthesia Monitor with L-ANE03 and L-ANE03A software is indicated for use by qualified medical personnel only.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K030812